

RESPONSE

I. Status of the Claims

Prior to the Action, claims 1-19 were pending. Presently, no claims have been amended, canceled or added. Claims 1-19 are therefore pending in the case.

As no claims have been amended, canceled or added, an additional copy of the pending claims is not necessary under 37 C.F.R. § 1.121(c).

II. Rejoinder of All Claims

The earlier Restriction and Species Election Requirement ("the Requirement") restricted the product and process claims within original claims 1-19 into two distinct inventions. Applicants elected the products of Group I. The Requirement also set forth three species elections, and Applicants responded with remarks and elections from Species A, Species B and Species C.

Claims 1-5, 9, 12 and 13 have already been examined, and no substantive rejections have been entered (the only rejection of record simply requiring a follow-up declaration regarding the ATCC deposit already documented in full in the specification as filed). Accordingly, examination could have already proceeded to include claims 6-8, 10, 11 and 14-19.

Nonetheless, as the only rejection in the case is hereby overcome by the enclosed declaration, claim 1, and all claims dependent thereon, are in condition for allowance. Accordingly, claims 6-8, 10, 11 and 14-19 must now be rejoined in the case. As to the withdrawn process claims, independent process claim 14 includes all the limitations of independent product claim 1 and rejoinder is therefore proper (Requirement at page 4; Action at page 2).

III. Priority

The Action at page 3 alleges that the first priority application, U.S. application Serial No. 09/613,430, filed July 10, 2000 ("the first priority application"), does not disclose the 3G4 antibody. The Action then states, "the examiner has established the effective priority dated [sic] as July 15, 2002, the filing dated [sic] of the instant application"¹ (Action at page 3, emphasis as in original).

The Action's assessment of priority is flawed for at least two reasons.

Firstly, the initial consideration of the priority issue is improper. A claim for priority is only pertinent when "intervening art" is cited, *i.e.*, art that has an effective date between the filing date of the cited priority application and the filing date of the application undergoing examination. As no art rejections have been entered, let alone any based upon allegedly intervening art, the priority issue was improperly raised.

Secondly, and importantly, the Action's assessment of priority is factually incorrect. The denial of priority is presumably based on whether there is a literal instance of the exact term "3G4" in the first priority application. Such an analysis is erroneous, as it is the disclosure of the biological material that is required, not continuity of the exact terminology applied by the inventors or others to the biological material.

The 3G4 antibody, *i.e.*, the biological material, was disclosed in the first priority application at least at Example XV. Note, in particular, the antibody termed "F3-G4" in Table 8. This initial designation was later shortened to "3G4" (the "F" in "F3-G4" simply stands for "fusion", and this part of the name was dropped as being applicable to all monoclonals and therefore redundant). The "F3-G4" antibody in the first priority application and the "3G4"

¹The filing date of the instant application is July 15, 2003; and the July 15, 2002 date presumably refers to the second priority application, U.S. provisional application Serial No. 60/396,263, filed July 15, 2002.

antibody in the present application are thus one and the same biological material (see also, enclosed Declaration of Biological Culture Deposit by Philip E. Thorpe).

As no intervening art has been cited, the issue of the effective priority date for the present application is moot. In any event, the effective priority date has been clearly established to be July 10, 2000, the filing date of the first priority application.

IV. Rejection of Claims 1-5, 9, 12 and 13 Under 35 U.S.C. § 112, First Paragraph

The only rejection in the case is of claims 1-5, 9, 12 and 13 under 35 U.S.C. § 112, first paragraph, as allegedly lacking complete evidence of the deposit of biological materials. Although Applicants respectfully traverse, the rejection is overcome.

The Action alleges that the specification lacks "complete evidence" of deposit, "complete deposit information" and that amendment of the specification is required (Action at page 4, lines 1-3; page 5, lines 18-19). Applicants cannot see how such conclusions could be reached, as the specification lists the name and address of the depository, the depositor, the dates of submission, the dates of receipt, the viability, the ATCC accession number, that the deposit was made under the provisions of the Budapest Treaty and that the hybridoma "will be made available by the ATCC under the terms of the Budapest Treaty upon issue of a U.S. patent with pertinent claims".

As to the Action's requirement for a declaration stating that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application (Action at page 4, last paragraph), Applicants provide herewith the Declaration of Biological Culture Deposit by Philip E. Thorpe, where Dr. Thorpe makes the appropriate statements.

The rejection under 35 U.S.C. § 112, first paragraph is therefore overcome and should be withdrawn.